5.0 510(k) Summary

APR 16 2014

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 316-3690 (801) 826-4112 Mr. Cory Marsh February 24, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Rotating Adapter Adapter/Connector Cardiopulmonary bypass adapter, stopcock, manifold or fitting
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Rotator; male-male, male-female Cardiopulmonary bypass adapter, stopcock, manifold or fitting K932251 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.4290 FDA Product Code: DTL Review Panel: Cardiovascular	
Intended Use	Merit's Rotating Adapters are indicated for use in interventional, diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.	
Device Description	Merit's Rotating Adapters are marketed in two configurations: Male-Male Adapter (MMA) and Male-Female Adapter (MFA). The adapters are comprised of a stand-alone rotator assembly bonded to a polycarbonate male or female luer lock, using a UV cured adhesive. The stand-alone rotator assembly is comprised of individually molded polycarbonate parts (housing connector, retaining collar, hub) and an EPDM (Ethylene Propylene Diene Monomer) O-Ring.	

Comparison to Predicate Device	The technological characteristics of the subject device are identical to the predicate device. Both devices use the same components and materials, with the exception of the O-Ring, which has undergone a material change from silicone to EPDM. Both devices have the same mode of operation and indications for use.
Safety & Performance Tests	No special controls have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Rotating Adapters was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 8536-4:2010, *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed* • ISO 8536-10:2004, *Infusion equipment for medical use – Part 10: Accessories for fluid lines for use with pressure infusion equipment* • ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – routine control of a sterilization process for medical devices* • ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995 • ISO 10993-4:2002 (Amd.1:2006), *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood* • ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* • ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* • ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* • ASTM F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials* • United States Pharmacopeia 36, National Formulary 31, 2013 <151> Pyrogen Test

Safety & Performance Tests cont.	Device Testing • Merit Rotational Torque Test • Merit Hydrostatic Pressure Test • Merit Vacuum Leak Test • ISO 8536-4 Chemical Requirements • ISO 8536-10 Particulate • ISO 8536-10 Leakage Biocompatibility • Cytotoxicity • Sensitization • Irritation • Systemic Toxicity • Systemic Injection • Pyrogenicity • Hemocompatibility • Chemical Characterization The results of the testing demonstrated that the Rotating Adapters met the predetermined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Rotating Adapters meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Rotator, K932251, manufactured by Merit Medical Systems, Inc..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Merit Medical Systems, Inc.
Mr. Cory Marsh
Regulatory Affairs Specialist
1600 West Merit Pkwy.
South Jordan, UT 84095 US

Re: K140475
Trade/Device Name: Rotating adapters; male-male, male-female
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold or fitting
Regulatory Class: Class II
Product Code: DTL
Dated: February 24, 2014
Received: February 26, 2014

Dear Mr. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Diseases
Office of Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if known): _____

Device Name:

Indications for Use: K140475

Merit's Rotating Adapters are indicated for use in interventional, diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)510(k) Summary

Bram D. Zuckerman -S
2014.04.16 10:40:19
-04'00'